REMARKS

Claims

Claims 1-4 and 6-14 are under examination with claims 5 and 15-20 withdrawn from consideration due to restriction/election. Claims 21-28 are added by this paper.

Claim amendments

The claims have been amended to conform to conventional US practice and to correct obvious typographical errors. Use claims 10-17 have been converted into US process claims. Entry thereof is respectfully requested.

New claim 21 recites the subject matter cancelled via amendment of claim 4. Claim 22 is supported, at least, by the disclosure contained in the Examples.

The amended claims are supported by the entirety of Applicants' disclosure, as originally filed. For example, support for the method(s) claimed in Applicants' instant claims 10–13 can be found in, for example, page 11, 1st paragraph (claim 10); page 12, 2nd paragraph (claim 11); page 13, 2nd paragraph (claim 12); and the paragraphs bridging pages 18-19 in the RESULTS section (claim 13) of Applicants' instant specification, as originally-filed.

Furthermore, support for the molecular markers recited in claims 1 and 10–13 can be found in, for example, page 5, 4th paragraph; support for diseases/disorders recited in claims 10-13 and the new dependent claims 23-27, can be found in, for example, page 7, 2nd and 3rd paragraphs of the specification, as originally-filed.

It is respectfully submitted that the claim amendments do not raise new matter.

Specification

Applicants have amended the specification and the claims to conform to the sequence disclosure requirements. A copy the sequence disclosure in paper, along with an electronic text file containing the same, is enclosed with this submission. Withdrawal of the objection is respectfully requested.

Rejection under §101

The Examiner is thanked for her careful review of the claims. The rejection is moot

in view of the amendments. Withdrawal of the rejection is respectfully requested.

Rejection under §112, ¶2

With respect to a disclosure of SEQ ID NOs in the claims, Applicants courteously traverse this requirement. Insofar as the claim terms HDAC and HDAC-2 are well-recognized in the art, and further in view of the fact that the polypeptide/nucleotide sequences directed to such molecules are disclosed in the Applicants' own specification (for example, sequence disclosure), it is kindly submitted that the meaning(s) of the terms is well-understood in the art. Explicit recitation of sequence identifiers and/or other structural parameters in the claims is not necessary.

It is respectfully submitted that the various other rejections under §112, ¶2, which are not specifically discussed herein, are moot in view of the amendment of the claims. Withdrawal of the rejection is respectfully requested.

Rejection under §112, ¶1

Claims 1–4 and 6–14 stand rejected under §112, ¶1 as allegedly lacking a written description of the term "molecular marker." It is respectfully submitted that the rejection is moot in view of the amendments.

Rejection under §102(b)

Claims 1–4 and 6–14 stand rejected under §102(b) as allegedly being anticipated by MacLeod (WO 00/71703). Applicants respectfully traverse this rejection.

MacLeod is drawn to inhibition of HDAC at the nucleic acid level. See, page 3, lines 2–5 of MacLeod et al. Example 2 of MacLeod discloses inhibition of HDAC activity using "antisense oligonucleotides." The disclosure in Example 3, which the Office Action relies on in levying the rejection, is directed to the use of "second generation antisense oligonucleotides." According to MacLeod, the second generation oligonucleotides, which comprise "phosphothionate linkers," are allegedly more stable than those anti-sense molecules utilized in Example 2 of the reference. The cited reference fails to mention any inhibitor, let alone an HDAC inhibitor which is capable of effecting the modulating the expression of the molecular markers in a manner described in Applicants' claims. For

example, in the 2nd paragraph of Example 3, MacLeod explicitly states that antisense molecules are capable of inhibiting *protein expression*. A skilled artisan will appreciate that MacLeod's method of genetic manipulation of protein levels (using antisense technology) is fundamentally distinct from Applicants' disclosed technique of modulation of enzyme activity using chemical (i.e., small molecule) inhibitors. For example, the pharmacological differences between the two approaches, both at the molecular and the physiological level, are well-recognized in the art.

Applicants' claims are directed to a method of characterization of an HDAC inhibitor or a potential HDAC inhibitor comprising measuring the amount of markers such as HDAC. As described in the instant specification and the Examples contained therein, the method comprises the characterization of an inhibitor which modulates the *catalytic activity* of HDAC. There is no mention in MacLeod that such antisense molecules interfere with the catalytic activity of the HDAC protein.

Since all material elements of the claims are not disclosed in the cited reference, the teachings of MacLeod cannot anticipate or render obvious the methods taught by the instant invention. Thus, the present invention is not anticipated by MacLeod et al.

All the rejections should therefore be withdrawn.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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